

# GETNICK & GETNICK LLP

## Fraud in the Pharmaceutical Industry

### The United States *qui tam* Whistleblower Law

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## Outline

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- ▶ Pharma Fraud Overview
- ▶ The False Claims Act *Qui Tam* Whistleblower Law
- ▶ FCA *Qui Tam* Pharma Fraud Settlements 2000-2012
- ▶ Who are the Whistleblowers?
- ▶ Case Study: *U.S. ex rel. Eckard v. GlaxoSmithKline*, 04 CV10375 (JLT) (D.Mass.)
- ▶ Preventing Pharma Fraud

## Fraud by Pharma

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- ▶ Illegal marketing and promotion
- ▶ Kickbacks to health care providers and others
- ▶ Distributing adulterated drugs
- ▶ Overcharging government health programs
- ▶ False or misleading clinical data provided to FDA and consumers
- ▶ Price fixing and monopoly practices

## False Claims Act *Qui Tam* Law

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- ▶ Creates a civil cause of action for fraud on the government
- ▶ Treble damages and penalties of \$5,500-\$11,000 per violation
- ▶ Action can be brought both by the government and by a private citizen in the name of the government (the *qui tam* “relator”)
- ▶ Relator is entitled to receive up to 30% of the proceeds plus attorneys fees and costs
- ▶ 15% minimum share (with exceptions)

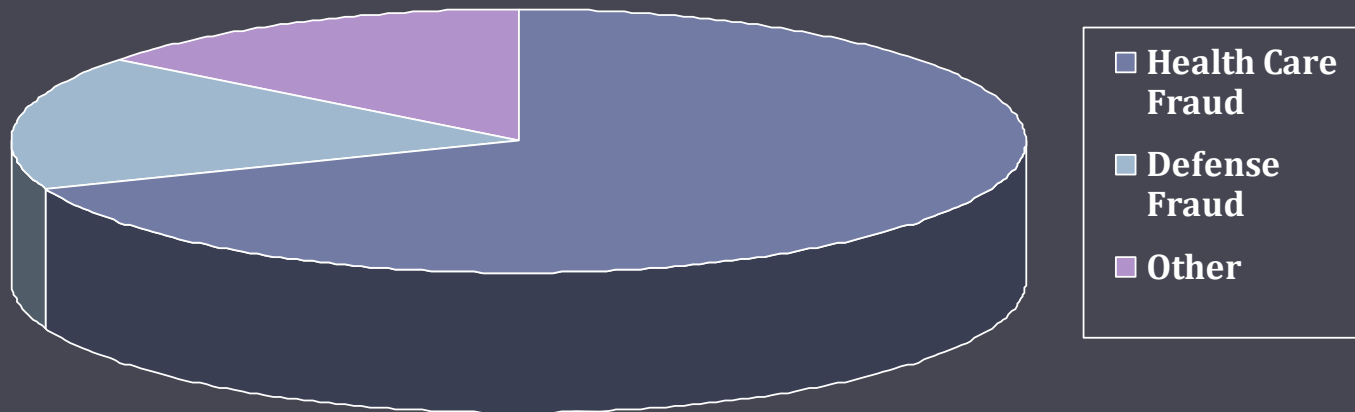
## A Short History

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- ▶ Passed by the Lincoln Administration in 1863.
  - ▶ The *qui tam* law is “firmly rooted in the American legal tradition.”
- ▶ A bi-partisan initiative: strengthened by Reagan in 1986 and Obama in 2009
  - ▶ The *qui tam* law is a “public-private partnership.”
- ▶ 29 States and the District of Columbia now have *qui tam* statutes.

# FCA Recoveries 1987-2012

- ▶ Total: \$35 billion
  - ▶ \$24 billion qui tam
- ▶ Health Care Fraud: \$24 billion
  - ▶ \$18 billion qui tam
- ▶ Defense Fraud: \$5 billion
- ▶ Other: \$6 billion



## *Qui Tam* Procedure

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- ▶ Relator files Complaint under seal in federal court and serves the Complaint and statement of material facts on DOJ
- ▶ DOJ investigates and decides whether to intervene in the action or decline to do so
- ▶ Relator may proceed if DOJ declines

## Checks and Balances

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- ▶ Cases are barred if the allegations are substantially the same as those:
  - ▶ on the public record
  - ▶ in an existing filed case
- ▶ Defendant may recover attorneys fees and costs from relator if case is “frivolous or vexatious”

more ...



## Checks and Balances (cont.)

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- ▶ Relator who “planned and initiated” the violations may receive zero, in the court’s discretion
- ▶ Relator who is criminally convicted in relation to the violations must receive zero

## Potential Collateral Consequences

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- ▶ Criminal prosecution
- ▶ Corporate Integrity Agreements
- ▶ Class/shareholder/SEC/private insurer actions
- ▶ Exclusion from federal programs
- ▶ Foreign Corrupt Practices Act actions
- ▶ Cessation of conduct and deterrence

## Pharma Fraud *Qui Tam* Cases

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More than \$20 billion in civil recoveries and  
criminal fines between 2000 and 2012

Pharmaceutical Company	Date Settled	Primary Fraud Alleged	Whistleblower/s	Criminal Fine	Civil Settlement	Total Recovery
GlaxoSmithKline	7/2/2012	Off-label promotion; kickbacks; failing to report safety data; pricing fraud	4 GSK employees, incl. Snr Marketing Manager and Regional VP	\$1 Billion	\$2 Billion	\$3 Billion
Pfizer	9/2/2009	Off-label promotion; kickbacks	Several Pfizer sales reps	\$1.3 Billion	\$1 Billion	\$2.3 Billion
Abbott Laboratories	5/7/2012	Off-label promotion; kickbacks	Several Abbott sales reps	\$800 Million	\$800 Million	\$1.6 Billion
Eli Lilly	1/15/2009	Off-label promotion; kickbacks	Several Eli Lilly sales reps	\$615 Million	\$800 Million	\$1.415 Billion
Merck	11/22/2011	Off-label promotion	Unidentified whistleblower(s)	\$ 321.6 Million	\$628.3 Million	\$950 Million
TAP Pharmaceuticals	10/3/2001	Marketing the spread; kickbacks	TAP V-P of Sales and HMO Medical Director	\$290 Million	\$585 Million	\$875 Million
GlaxoSmithKline	10/26/2010	Manufactured and sold adulterated drug products	GSK Global Quality Assurance Manager	\$150 Million	\$600 Million	\$750 Million
Serono	10/17/2005	Off-label promotion; kickbacks	5 Serono employees (Lab and Sales)	\$136.9 Million	\$567 Million	\$704 Million
Merck	2/7/2008	Concealing Best Price; kickbacks	Merck District Sales Manager/Physician		\$650 Million	\$650 Million
Allergan Inc.	9/1/2010	Off-label promotion; kickbacks	Allergan Managers and consultant	\$375 Million	\$225 Million	\$600 Million
AstraZeneca	4/27/2010	Off-label promotion; kickbacks	AstraZeneca sales rep		\$520 Million	\$520 Million
Bristol-Myers Squibb	7/28/2007	Off-label promotion; marketing the spread	Independent Pharmacy and others		\$515 Million	\$515 Million
Schering Plough	8/29/2006	Concealing Best Price; off-label promotion	3 Schering Plough sales reps	\$180 Million	\$255 Million	\$435 Million
Warner-Lambert	5/13/2004	Off-label promotion; kickbacks	Warner Lambert Medical Liaison	\$240 Million	\$190 Million	\$430 Million
Cephalon	9/29/2008	Off-label promotion; kickbacks	3 Cephalon sales representatives	\$50 Million	\$375 Million	\$425 Million
Novartis Pharmaceuticals	9/30/2010	Off-label promotion; kickbacks	Former sales representatives	\$185 Million	\$237.5 Million	\$422.5 Million
Abbott, B. Braun and Roxane Laboratories	12/7/2010	Marketing the spread	Independent pharmacy		\$421.1 Million	\$421.1 Million
Elan	7/15/10 & 12/15/10	Off-label promotion	Physician	\$100 Million	\$317.5 Million	\$417.5 Million

# Off-label Marketing/Kickbacks

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- ▶ Marketing FDA-approved drug for non-FDA approved purposes
- ▶ Cases:
  - ▶ Pfizer
  - ▶ Ely Lilly
  - ▶ Serono
  - ▶ Allergan
  - ▶ AstraZeneca
  - ▶ Bristol Myers
  - ▶ Schering Plough
  - ▶ GSK
  - ▶ Cephalon
  - ▶ J&J
  - ▶ Novartis
  - ▶ Alpharma
  - ▶ Intermune
  - ▶ Elan
  - ▶ Forest
  - ▶ Merck

## Pricing/Kickbacks (AWP)

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- ▶ Inflating the price paid by the government (the “AWP”) while discounting to other purchasers.
- ▶ “Marketing the spread”
- ▶ Cases:
  - ▶ TAP
  - ▶ AstraZeneca
  - ▶ Aventis
  - ▶ Bristol Meyers Squibb
  - ▶ Abbott
  - ▶ Mylan
  - ▶ GlaxoSmithKline
  - ▶ Schering Plough
  - ▶ Teva
  - ▶ Actavis
  - ▶ Bayer
  - ▶ PAR
  - ▶ Sandoz

## Pricing/Kickbacks (“Best Price”)

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- ▶ Concealing the “Best Price” paid by commercial customers
  - ▶ “Private Labeling”
    - ▶ Bayer
    - ▶ GSK
  - ▶ Rebates and grants to HMOs
    - ▶ Schering Plough/Pfizer/TAP
  - ▶ Nominal Pricing
    - ▶ Merck

## Adulterated Drugs

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- ▶ Failure to follow current Good Manufacturing Practices (cGMPs) resulting in government paying for adulterated drugs
- ▶ Case: GlaxoSmithKline



# Who are the Whistleblowers?

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- ▶ Corporate employees (current, former)
- ▶ Customers, e.g., doctors, pharmacists, HMO employees
- ▶ Patients
- ▶ Competitors



# Executives and Managers

Company	Year	Relator	Recovery
Columbia/HCA	2003	Divisional Reimbursement Supervisor/Hospital CFO	\$881M
TAP	2001	TAP V-P of Sales/HMO Medical Director	\$875M
GlaxoSmithKline	2010	Global Quality Assurance Manager	\$750M
Columbia/HCA	2000	V-P of affiliated home health company/Others	\$745M
Merck	2008	Merck District Sales Manager/Physician	\$650M
Allergan	2010	Allergan Policy Manager and Account Manager	\$600M
Gambro	2004	Chief Medical Officer	\$350M
Schering Plough	2004	Three Schering Senior Managers	\$345M
SmithKlineBeecham	1997	SKB Medical Director/Senior Billings System Analyst	\$325M
Bayer	2003	Bayer Corporate Marketing Executive	\$257M
National Health Labs	1992	NHL Sales Manager	\$149M
King	2004	King Director of Contracts and National Accounts	\$124M
Pfizer	2002	Pfizer National Account Manager	\$49M

Case Study: U.S. et al. ex rel. Cheryl Eckard v. GlaxoSmithKline and SB Pharmco Puerto Rico

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- ▶ *Qui Tam* case filed February 2004 by former Manager of Global Quality Assurance
- ▶ \$750 million settlement and plea October 2010
  - ▶ \$600 million civil settlement resolved allegations that GSK sold the government four products that were adulterated: Bactroban, Kytril, Avandamet and Paxil CR
  - ▶ \$150 million criminal fine and guilty plea by SB Pharmco to releasing batches of those products in interstate commerce with intent to defraud and mislead

## Preventing Pharma Fraud: which of these strategies will work best?

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- ▶ Criminally prosecute executives
- ▶ Exclude pharma companies and executives from government programs
- ▶ Pass more laws and regulations
- ▶ Strengthen laws that work
- ▶ Give regulatory and enforcement agencies more resources
- ▶ Self-regulation and effective corporate compliance programs

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Questions?

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